

Appl. No. 10/802,166
Atty. Docket No. 9184M&
Amdt. dated June 22, 2011
Reply to Office Action of December 22, 2010
Customer No. 27752

REMARKS

Claim Status

Claims 1, 3, 7-13, 18-25 and 27 are pending in the present application. No additional claims fee is believed to be due.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 U.S.C. §103(a) Over WO 01/00151 (hereinafter “Gavin et al.”) and WO 96/25913 (hereinafter “Bhat et al.”)

Claims 1, 3, 7-13, 18-25 and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over WO 01/00151 (hereinafter “Gavin et al.”) and WO 96/25913 (hereinafter “Bhat et al.”).

The Office Action concedes that Gavin et al. do not expressly teach a composition comprising the zinc-containing layered material basic zinc carbonate as instantly claimed, nor zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof. The Office Action however asserts that the deficiency in Gavin et al. is cured by the teachings of Bhat et al. It is further asserted that one of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition, but not specifically basic zinc carbonate and alleges that Bhat et al. cures this deficiency by teaching the synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos. The Office action further asserts that the ‘zinc lability’ is an intrinsic property of the zinc salts of Gavin et al. since they are the same as instantly claimed. Applicants respectfully traverse this rejection.

Gavin et al. discloses a topical composition for the treatment of antimicrobial infections on the skin or scalp which includes a polyvalent metal salt of pyrithione, such as zinc pyrithione and a metal ion source. According to Gavin et al. the metal ion source can be a zinc salt. Suitable zinc salts are listed at page 7, first paragraph of Gavin et al. However, none of

Appl. No. 10/802,166
Atty. Docket No. 9184M&
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Customer No. 27752

the zinc salts disclosed in Gavin et al. are zinc-containing layered materials as required by the instant claims. In fact, Gavin et al. is completely silent as to the use of any zinc-containing layered materials for any purposes. In this regard, the Office Action cites Bhat et al. and asserts that one skilled in the art would add the zinc hydroxycarbonate disclosed in Bhat et al. to the composition disclosed in Gavin et al. to allegedly arrive at the claimed invention. Applicants respectfully traverse the rejections.

Bhat et al. in WO 96/25913 describes the preparation and use of a material termed “monophasic zinc hydroxycarbonate.” As described by Bhat et al., hydrozincite (naturally occurring) and basic zinc carbonate are equivalent names for zinc hydroxycarbonate (Page 1, lines 23-24 and line 35). The term “monophasic” is defined (Page 1, lines 29-33) as “without any other impurity phases ... present ...”.

Applicants further submit a Declaration under 37 C.F.R. 1.132 from James R. Schwartz in support against the present Office Action assertions.

In the 1.132 Declaration submitted herein, to establish the impact that changes in zinc lability of basic zinc carbonate materials has on efficacy, an *In Vivo* Malassezia Automated Counting (IMAC) data from a study was correlated to the measured zinc lability values of various basic zinc carbonate materials found in the present invention and further discussed in the previous filed 1.132 Declaration of September 30, 2010.

Data from the *In Vivo* Malassezia Automated Counting (IMAC) method measures the ability of an anti-dandruff product to reduce the population of Malassezia yeast on the scalp. There is a very strong relationship between reduction in Malassezia levels and resultant clinical efficacy (reduction in flake symptoms). Thus IMAC Malassezia reduction is a proxy measurement for anti-dandruff efficacy.

In this IMAC Study, shampoo prototypes that differed only in the source of the basic zinc carbonate were evaluated for *in vivo* Malassezia reduction capability. This data is tabulated in the 1.132 Declaration in comparison to the zinc lability data for basic zinc carbonate materials of different origin and disclosed in the present invention, namely

Appl. No. 10/802,166
Atty. Docket No. 9184M&
Amdt. dated June 22, 2011
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Customer No. 27752

Bruggemann, Elementis, and Cater. Bruggemann is an “impurity containing” basic zinc carbonate, wherein Elementis and Cater are more *without any other impurity* phases or monophasic.

As demonstrated in the Table 1 and Graph 1 of the 1.132 Declaration, there is a significant reduction in Malassezia count for Bruggemann at 251.2 when compared to Cater at 155.7 and Elementis at 214.1. The data indicates a strong correlation between *zinc lability* and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions.

A basic zinc carbonate *without any other impurity* phases or monophasic, such as those from Elementis and Cater, do not possess the same efficacy as an impurity containing basic zinc carbonate, such as Bruggemann as evidenced by the supporting data in the 1.132 Declaration. Such differences of basic zinc carbonate without impurities (monophasic such as Cater and Elementis) vs. impurity containing basic zinc carbonate (e.g. Bruggemann) are important to the behavior of basic zinc carbonate, as the higher purity materials (closer to monophasic) have lower IMAC Efficacy (Reduction in Malassezia Count), as demonstrated in Table 1 and Graph 1.

As the present 1.132 Declaration states, this data demonstrates that Bruggemann-type basic zinc carbonate materials, which are impurity containing, are an important attribute of the claimed invention to achieve high performance.

Further, there is no motivation to combine the teaching of Gavin et al. with Bhat et al. and arrive at the claimed invention, as neither Gavin et al. nor Bhat et al. disclose an impurity containing hydroxy-containing basic zinc carbonate. Accordingly, the rejection is untenable and should be withdrawn.

Double Patenting

1) Claims 1, 3, 7-13, 18-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 8-12, 16-32 and 34-39 of

Appl. No. 10/802,166
Atty. Docket No. 9184M&
Amdt. dated June 22, 2011
Reply to Office Action of December 22, 2010
Customer No. 27752

copending Application No. 11/602,770. This co-pending application is jointly owned by The Procter & Gamble Company and Arch Chemicals, Inc. As all of the rejections are provisional, Applicants will respond if and when any allowable subject matter is identified. Therefore, Applicants requests that the provisional, obvious-type double patenting rejection be held in abeyance, until indication of allowable subject matter.

2) Claims 1, 3, 7-13, 18-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 9, 13-30, 35 and 37-40 of copending Application No. 11/890,684.

Claim 1 of the Application 11/890,684 is directed to a composition comprising an effective amount of a particulate zinc material; an effective amount of a surfactant including a surfactant with an anionic functional group; an effective amount of a pyrithione or a polyvalent metal salt of a pyrithione; from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm; and from about 20% to about 95% of an aqueous carrier, by weight of said composition.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the impurity containing basic zinc carbonate has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to impurity containing basic zinc carbonate is greater than or equal to 2 to 1. Applicants point out that Claim 1 above, as now amended, is the same as Claim 26, now canceled. Claim 26 has not been included in this obvious type double patenting rejection.

The currently claimed invention does not require from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm, as required in

Appl. No. 10/802,166
Atty. Docket No. 9184M&
Amtdt. dated June 22, 2011
Reply to Office Action of December 22, 2010
Customer No. 27752

the '684 application. In the '684 application, the surprising discovery that compositions combining certain water soluble or dispersible, cationic, non crosslinked, deposition polymers in combination with surfactants form microscopically-phase separate lyotropic liquid crystals suspended in an aqueous surfactant phase is clearly patentably distinct. In use, the dispersed, concentrated polymer lyotropic liquid crystal phase provides improved hair and skin conditioning. The '684 invention is *not a matter of routine optimization and is not mere optimization of the amount of an ingredient to arrive at a desired result.*

Further, the '684 application is not directed to or requires a relative zinc lability of greater than about 15% for an impurity containing basic zinc carbonate. Yet further, the '684 application does not require a zinc-containing layered material *wherein the zinc-containing layered material is an impurity containing basic zinc carbonate and mixtures thereof or a ratio of surfactant to impurity containing basic zinc carbonate of greater than or equal to 2:1.* In contrast, the currently claimed invention requires the limitation of *a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate.* Applicants have provided data herein in the 1.132 Declaration to demonstrate that all forms of basic zinc carbonate do not result in the same zinc lability and thus do not result in the same efficacy. This data indicates a strong correlation between zinc lability and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions.

A basic zinc carbonate without any other impurity phases or monophasic, such as those from Elementis and Cater, do not possess the same efficacy as an impurity containing basic zinc carbonate, such as Bruggemann as evidenced by the supporting data in the 1.132 Declaration.

These 2 claim sets are patentably distinct and each of the specification and *data* demonstrate that the determination of liquid crystal phase in the '684 application or the ratio of surfactant to impurity containing basic zinc carbonate and relative zinc lability as required in the currently claimed invention are *not a matter of routine optimization and is not mere optimization of the amount of an ingredient to arrive at a desired result.*

Appl. No. 10/802,166
Atty. Docket No. 9184M&
Amdt. dated June 22, 2011
Reply to Office Action of December 22, 2010
Customer No. 27752

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

3) Claims 1, 3, 7-13 and 18-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899,106.

Claim 1 of the Application 11/899,106 is directed to a composition comprising an effective amount of a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25°C; from about 5% to about 50% of a surfactant; and from about 40% to about 95% water; wherein the pH of the composition is greater than about 7.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the impurity containing basic zinc carbonate has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to impurity containing basic zinc carbonate is greater than or equal to 2 to 1. Applicants point out that Claim 1 above, as now amended, is the same as Claim 26, now canceled. *Claim 26 has not been included in this obvious type double patenting rejection.*

The currently claimed invention is not directed to a composition comprising a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25°C. In contrast, the currently claimed invention requires the limitation of *a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate.* Applicants have provided data herein in the 1.132 Declaration to demonstrate that all forms of basic zinc carbonate do not result in the same zinc lability and thus do not result in the same efficacy. This data indicates a strong correlation

Appl. No. 10/802,166
Atty. Docket No. 9184M&
Amdt. dated June 22, 2011
Reply to Office Action of December 22, 2010
Customer No. 27752

between zinc lability and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions.

A basic zinc carbonate without any other impurity phases or monophasic, such as those from Elementis and Cater, do not possess the same efficacy as an impurity containing basic zinc carbonate, such as Bruggemann as evidenced by the supporting data in the 1.132 Declaration.

Further, the '106 application claims require that the zinc containing material have an aqueous solubility within the composition of less than about 25% by weight at 25°C. The '106 application does not require a relative zinc lability of greater than about 15% for an impurity containing basic zinc carbonate, as required in the currently claimed invention. Yet further, the '106 application does not require the amount of *a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate or* a ratio of surfactant to impurity containing basic zinc carbonate of greater than or equal to 2:1. These two claim sets are patentably distinct.

These 2 claim sets are patentably distinct and the present specification and *data* demonstrate that the determination of the ratio of surfactant to impurity containing basic zinc carbonate as required in the currently claimed invention are *not a matter of routine optimization and is not mere optimization of the amount of an ingredient to arrive at a desired result.*

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection 103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1, 3, 7-13, 18-25 and 27 is respectfully requested.

Appl. No. 10/802,166
Atty. Docket No. 9184M&
Amdt. dated June 22, 2011
Reply to Office Action of December 22, 2010
Customer No. 27752

Respectfully submitted,

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